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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PACESETTER, INC.  
15900 Valley View Court  
Sylmar, CA 91392-9221

EXAMINER

BRADFORD, RODERICK D

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/077,660

Applicant(s)

PARK ET AL. *ch*

Examiner

Roderick Bradford

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 5-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 14-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1-5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species of the claimed invention: Embodiments 1-9, represented by a physiological sensor that measures physical motion, QT interval, cardiac conductivity, cardiac contractility, evoked response amplitude and duration, stroke volume, paced depolarization integral, blood oxygen concentration and blood carbon dioxide, respectively.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic and allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Derrick Reed on September 25, 2003 a provisional election was made without traverse to prosecute the invention of Embodiment 1, claims 1-4 and 14-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 3, 4, 12, 14, 17, 18, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourgeois et al. U.S. Patent No. 6,126,611.

Referring to claims 1, 14 and 18, Bourgeois discloses an implantable cardiac stimulation device for stimulating the heart comprising:

- a physiological sensor that is capable of sensing a physiological parameter and generating corresponding signals (column 3, lines 23-34)
- one or more pulse generators that are capable of generating cardiac pacing pulses (column 2, lines 38-41)
- circuitry connected to the sensor that is operative to detect a potential sleep apnea condition based on the signals and that is responsive to detection of a potential sleep apnea condition to control the one or more pulse generators to pace the heart at a sleep apnea prevention rate (column 6, lines 20-36).

Referring to claim 2, further comprising a controller coupled to the one or more pulse generators and to the physiological sensor, the controller comprising an executable control logic that distinguishes between a sleeping condition and a waking condition of a patient and controls the one or more pulse generators to pace at a sleep apnea prevention rate in response to detection of a sleeping condition (column 5, lines 65-67 and column 6, lines 1-4).

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Referring to claims 3 and 21, further comprising one or more sensors capable of electric coupling to the cardiac tissue (column 4, lines 1-9) and including an executable control logic that controls the one or more pulse generators to pace at a rate selected from among at least a sleeping rate, resting rate and an exercise rate (column 5, lines 62-65), the executable control logic being capable of distinguishing between a sleeping condition and a waking condition (column 5, lines 65-67 and column 6, lines 1-4) and controlling the one or more pulse generators to pace at a rate greater than the resting rate in response to detection of a sleeping condition (column 6, lines 30-39).

Referring to claims 4 and 17, a physiological sensor that measures physical motion for derivation of an activity parameter and an activity variance parameter, and activates sleep apnea preventive pacing when the activity and the activity variance signals indicate a sleeping condition (column 5, lines 65-67 and column 6, lines 1-4).

Referring to claim 20, further comprising distinguishing between a sleeping condition and a waking condition (column 5, lines 65-67 and column 6, lines 1-4), timing generation of the cardiac pacing pulse and controlling the timed cardiac pacing pulses at a sleep apnea prevention rate (column 7, lines 9-13).

6. Claims 1, 2, 4, 14, 15, 16, 17, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonnet et al. U.S. Patent No. 6,574,507.

Referring to claims 1, 14 and 18, Bonnet discloses an implantable cardiac stimulation device for stimulating the heart comprising:

- a physiological sensor that is capable of sensing a physiological parameter and generating corresponding signals (column 4, lines 5-10)

- one or more pulse generators that are capable of generating cardiac pacing pulses (abstract)
- circuitry connected to the sensor that is operative to detect a potential sleep apnea condition based on the signals and that is responsive to detection of a potential sleep apnea condition to control the one or more pulse generators to pace the heart at a sleep apnea prevention rate (abstract).

Referring to claim 2, further comprising a controller coupled to the one or more pulse generators and to the physiological sensor, the controller comprising an executable control logic that distinguishes between a sleeping condition and a waking condition of a patient and controls the one or more pulse generators to pace at a sleep apnea prevention rate in response to detection of a sleeping condition (column 4, lines 5-10).

Referring to claims 4 and 17, a physiological sensor that measures physical motion for derivation of an activity parameter and an activity variance parameter, and activates sleep apnea preventive pacing when the activity and the activity variance signals indicate a sleeping condition (column 4, lines 54-67).

Referring to claims, 15 and 19, wherein the means for detecting a potential sleep apnea condition comprises means for detecting a sleep condition (column 4, lines 48-49).

Referring to claim 16, further comprising means for distinguishing between a sleeping condition and a waking condition of a patient (column 5, lines 1-6).

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*R. Bradford*

R.B.

September 25, 2003

*Angela D. Sykes*

ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700